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Filed : November 25, 2003

### REMARKS

The foregoing amendments and the following remarks are responsive to the Office Action dated May 31, 2007 (hereinafter, "Office Action"). Claims 1-15 and 24-27 remain pending in the present application, and new Claim 31 has been added, as further discussed below.

#### Amendments to Specification

Applicant has amended the Specification to correct informalities noted by the Applicant. These amendments do not add new matter.

#### Rejection of Claim 25 under 35 U.S.C. 112:

Claim 25 was rejected under 35 U.S.C. 112 as being indefinite for having insufficient antecedent basis. Claim 25 has been amended to overcome this basis for rejection.

#### Rejection of Claims 24-27 under 35 U.S.C. 102(b):

Claims 24-27 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,591,226 (hereinafter, "Trerotola"). Applicants respectfully disagrees with the rejection of these claims. Applicants respectfully disagrees with the rejection of these claims. However, to expedite the prosecution of the present application, Applicants have amended independent Claim 24 as described below. Applicants expressly reserve the right to further prosecute the original version of any Claims through continuation practice.

As amended, Claim 24 recites, in part, "an elongate, flexible catheter body, having a proximal end and a distal end and comprising an outer sheath and an inner core that is axially moveable with respect to the outer sheath, the catheter body further comprising a distal tip positioned near the distal end of the catheter and being coupled to the inner core; a self-expandable straight tube graft positioned in a compressed state within the distal end of the flexible catheter tubular body; a first graft restraint comprising a first peelable cover for restraining at least a first portion of the straight tube graft; wherein the first peelable cover is coupled to a first release element and wherein the first graft restraint is positioned within the catheter body in a graft loaded position."

In contrast, Trerotola discloses a method and apparatus for extravascular revision and de novo creation of arteriovenous shunts for hemodialysis and other applications (see 1:48-1:50). In other words, Trerotola discloses an apparatus and method of passing a graft through an *extravascular* lumen tunneled through body tissue below skin level and implanting opposing

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ends of a graft into a vessel at different locations so as to direct blood flow around a portion of the vessel.

With respect to Claim 24, Trerotola does not disclose or suggest all of the elements set nor are the elements arranged as required by the claim. *See* MPEP 2131. For example, Trerotola discloses a vascular access means that comprises short, tubular object. The body implantable device 2 is not positioned within the distal end of this object. Moreover, Trerotola does not disclose or suggest the use of a catheter body comprising an outer sheath, an inner core that is axially moveable with respect to the outer sheath and a distal tip coupled to the inner core as set forth in amended Claim 24. Trerotola also does not disclose or suggest a first graft restraint that is positioned within the catheter body in a graft loaded position. Therefore, Trerotola cannot anticipate Claim 24.

Regarding dependent Claims 25-27, respectfully stated, these claims are also not anticipated or suggested by Trerotola for at least the same reasons as stated above for Claim 24, on which these claims depend, and also because they each recite further patentable distinctions. Accordingly, Applicants submit that Claims 24-27 are in a condition for allowance over the references cited in the Office Action.

*Rejection of Claims 1-9 under 35 U.S.C. 103(a):*

Claims 1-8 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,720,735 (hereinafter, "Dorros") in view of U.S. Patent No. 5,647,857 (hereinafter, "Anderson") and Trerotola. Applicants respectfully disagree with the rejection of these claims. However, to expedite the prosecution of the present application, Applicants have amended Claims 1 and 10 as outlined below, and respectfully request the Examiner to reconsider and allow all of the above-listed claims in view of the foregoing amendments and the following comments. Applicants expressly reserve the right to further prosecute the original version of any Claims through continuation practice.

As amended, Claim 1 recites, in part, a bifurcation graft deployment system, comprising a catheter body having a proximal end and a distal end, an outer sheath, an inner core that is axially moveable with respect to the outer sheath, a bifurcated graft comprising a main vessel portion, a first branch vessel portion, and a second branch vessel portion that is positioned within the catheter body such that the main vessel portion is positioned nearer to the distal end of the

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catheter body in a graft loaded condition than either the first branch vessel portion or the second branch vessel portion.

In contrast, in Dorros, the stents are positioned in the opposite orientation – i.e., such that the diverging portions are positioned nearer to the distal end of the bifurcated catheter. The secondary references, Anderson and Trerotola, do not disclose a bifurcation graft system and thus they do not overcome the failure of Dorros to disclose the positioning of the bifurcated graft as set forth in Claim 1.

Moreover, the claimed arrangement is significantly different than Dorros because the stents, if arranged as set forth in Claim 1, would not be positionable in a bifurcated vessel as described in Dorros because the branched portions would be facing the opposite direction. Further, the claimed arrangement described above would not have been obvious to try, nor is it the result of substituting one known element for another to obtain predictable results. Because the bifurcation graft of Claim 1 is held within the catheter body in an opposite orientation as compared to the proposed combination, the bifurcation graft deployment system of Claim 1 is configured significantly differently as compared to the proposed combination. For example, because of the differing arrangement and structure of the features in Claim 1, the deployment system of Claim 1 can accommodate an outer sheath, which Dorros does not disclose or suggest. Further, due to the differing arrangement in the claimed system, the bifurcation graft deployment system of Claim 1 can be operated in a significantly different manner as compared to the proposed combination such that the bifurcated graft of Claim 1 is positioned in a different manner and the restraints are removed in a different manner and in an opposite direction as compared to the proposed combination.

Importantly, the claimed deployment system of Claim 1 has significant advantages as a result of this opposite arrangement, such as, allowing the bifurcated graft to be introduced only through a branch vessel as opposed to the main branch of the vessel. For example, this design allows the bifurcated graft to be introduced through one of the two iliac arteries below the aorta, which in some cases may be easier to access than the aorta and may result in less trauma to the patient. Furthermore, in some cases, because the first and second branches of the bifurcation graft deployment system of Claim 1 are positioned within a single outer sheath, in contrast with the combination proposed in the Office Action in which the branching stents occupy diverging

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sheaths, it can be easier for the bifurcated graft of Claim 1 to be moved through the network of vessels and accurately positioned at the location of the desired branching vessel without injury to the patient.

Accordingly, Applicants submit that one of skill in the art could not be reasonably expected to completely rearrange the elements of the cited art as suggested by the Examiner. Such a rearrangement is a significant modification of the prior art with no obvious or predictable advantage.

Applicants further submit that Claims 2-8 define patentable distinctions over the cited references, not only for the reasons stated above with respect to Claim 1, but also on their own merit. Accordingly, Applicants respectfully request the Examiner to withdraw the rejection of Claims 2-8 and to pass these claims to allowance.

Claim 9 was rejected under 35 U.S.C. 103(a) as being unpatentable over Dorros in view of Anderson and Trerotola as applied to Claim 8, and further in view of U.S. Patent No. 5,591,228 (hereinafter, "Edoga"). As with Dorros, Edoga discloses a bifurcated graft wherein the diverging portion of the graft is positioned nearer to the distal end of the graft carrying assembly. Thus, Edoga does not overcome the shortcomings noted above with respect to independent Claim 1. Accordingly, Applicants also respectfully request the Examiner to withdraw the rejection of Claim 9 and to pass this claim to allowance.

Rejection of Claims 10-15 under 35 U.S.C. 103(a):

Claims 10 and 12-15 were rejected under 35 U.S.C. 103(a) as being unpatentable over Dorros in view of U.S. Patent No. 5,026,377 (hereinafter, "Burton") and Trerotola. Applicants respectfully disagree with the rejection of Claims 10 and 12-15. Nevertheless, to advance prosecution, Applicants have amended Claim 10 as indicated below.

As amended, Claim 10 recites, in part, a bifurcated prosthesis having a main body section with proximal and distal ends and first and second branch sections at the proximal end of the main body section, wherein the compressed bifurcated prosthesis is positioned within the outer sheath such that the distal end of the bifurcated prosthesis is positioned nearer to the distal tip of the delivery catheter.

In contrast, as has been noted above, in Dorros, the stents are positioned in the opposite orientation – i.e., such that the diverging portions are positioned nearer to the distal end of the

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bifurcation catheter. Moreover, neither Burton nor Trerotola disclose a deployment system for deploying a bifurcated prosthesis and, accordingly, they do not overcome the failure of Dorros to disclose the arrangement described above.

As discussed above, one of ordinary skill in the art could not be reasonably expected to completely rearrange the parts as suggested in by the Office Action. Such an arrangement would defeat the intended use of the stents in Dorros because the stents, and, if arranged as set forth in Claim 1, would not be positionable in a bifurcated vessel as described in Dorros because the branched portions would be facing the opposite direction. Because the deployment system of Claim 10 is held within the catheter body such that the first and second branches point away from the distal end of the catheter, the deployment system of Claim 10 is necessarily configured differently as compared to the proposed combination, in which the diverging stents point toward the end(s) of the catheter.

For the reasons stated above, Applicants submit that Claim 10 defines patentable distinctions over the cited references and respectfully requests the Examiner to withdraw the rejection of Claim 10 and to pass Claim 10 to allowance. Applicants also submit that Claims 12-15 also define patentable distinctions over the cited references, not only for the reasons stated above with respect to Claim 10, but also on their own merit. Accordingly, Applicants respectfully request the Examiner to withdraw the rejection of Claims 10 and 12-15 and to pass these claims to allowance.

Claim 11 was rejected under 35 U.S.C. 103(a) as being unpatentable over Dorros in view of Burton and Trerotola as applied to Claim 10, and further in view of Edoga. However, as noted above, Edoga suffers from the same deficiencies as Dorros. Accordingly, Applicants submit that Claim 11 defines patentable distinctions over the cited references, not only for the reasons stated above with respect to Claim 10, but also on its own merit.

*Co-Pending Applications of Assignee:*

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

<b>Serial Number</b>	<b>Title</b>	<b>Filed</b>
11/417,651 ENDOLOG.007C4	ENDOLUMINAL VASCULAR PROSTHESIS	05-03-2006
11/623,679 ENDOLOG.007C5	ENDOLUMINAL VASCULAR PROSTHESIS	01-16-2007

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10/119,525 ENDOLOG.014C1	SELF EXPANDED BIFURCATED ENDOVASCULAR PROSTHESIS	04-08-2002
11/417,883 ENDOLOG.014C2	SELF EXPANDED BIFURCATED ENDOVASCULAR PROSTHESIS	05-03-2006
10/706,660 ENDOLOG.028C2	DUAL WIRE PLACEMENT CATHETER	11-12-2003
10/820,455 ENDOLOG.054A	ENDOLUMENAL VASCULAR PROSTHESIS WITH NEOINTIMA INHIBITING POLYMERIC SLEEVE	04-08-2004
11/104,303 ENDOLOG.056A	METHOD AND APPARATUS FOR DECOMPRESSING ANEURYSMS	04-12-2005
11/580,201 ENDOLOG.056CP1	METHOD AND APPARATUS FOR DECOMPRESSING ANEURYSMS	10-12-2006
11/522,292 ENDOLOG.067A	MULTI-SEGMENTED GRAFT DEPLOYMENT SYSTEM	09-15-2006
11/623,022 ENDOLOG.075A	DUAL CONCENTRIC GUIDEWIRE AND METHODS OF BIFURCATED GRAFT DEPLOYMENT	01-12-2007
60/947,317 ENDOLOG.081PR	GRAFT WITH ELECTRICAL SURFACE CHARGES	06-29-2007
60/981,869 ENDOLOG.085PR	STENT	10-23-2007
60/955,302 ENDOLOG.087PR	APPARATUS AND METHOD FOR RAPID RELEASE OF THERAPEUTIC AGENT INTO ANIMAL TISSUE	08-10-2007
60/987261 ENDOLOG.087PR2	APPARATUS AND METHOD FOR RAPID RELEASE OF THERAPEUTIC AGENT INTO ANIMAL TISSUE	11-12-2007
60/987268 ENDOLOG.091PR	METHOD AND AGENT FOR IN-SITU STABILIZATION OF VASCULAR TISSUE	11-12-2007
11/189,101 ENDOLOG.21CP6C2	BIFURCATION GRAFT DEPLOYMENT CATHETER	07-25-2005
11/417,926 ENDOLOG.21CP7C2	IMPLANTABLE VASCULAR GRAFT	05-03-2006
11/764,715 ENDOLOG.21CP7CC	IMPLANTABLE VASCULAR GRAFT	06-18-2007
10/690,227 ENDOLOG.23DV1C1	SINGLE PUNCTURE BIFURCATION GRAFT DEPLOYMENT SYSTEM	10-21-2003
11/214,427 ENDOLOG.4C3C1	BIFURCATED VASCULAR GRAFT AND METHOD AND APPARATUS FOR DEPOLYING SAME	08-29-2005

*No Disclaimers or Disavowals*

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

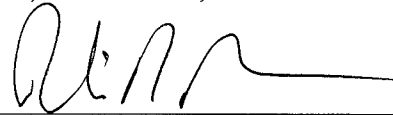
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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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